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EXAMINER	
GUDIBANDE, SATYANARAYAN R	
ART UNIT	**PAPER NUMBER**
1654	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/789,589	VAN ET AL.	
	Examiner	Art Unit	
	Satyanarayana R. Gudibande	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27* is/are pending in the application.

4a) Of the above claim(s) *8-10 and 12-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/27/04,2/23/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group II and election of structure I and SEQ ID NO: 8 as species in the reply filed on 9/10/07 is acknowledged. The traversal is on the ground(s) that the office requirement for an election of single polynucleotide is not applied to group II invention (claims 5-7 and 11). Applicants further state that none of the sequences in the sequence listing are polynucleotide. This is not found persuasive because upon further consideration, office noticed that the claims 1-4 (group I invention) are linking claims linking inventions II-IV. As per the linking claim analysis, the restriction has been modified to specify claims 1-4 as linking claims and would be examined along with group II (elected invention).

Claims 1-4 link(s) inventions II –IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-4. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable.

In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-27 are pending.

Claims 8-10 and 12-27 have been withdrawn from further consideration as being drawn to non-elected invention.

Claims 1-7 and 11 are examined on the merit.

The prior art search indicated that the formulae (I-IV) and the peptide species SEQ ID NO: 1 are free of art. However, the search was extended to other species and art was found on SEQ ID NO: 1 and has been applied to rejection under 35 USC 102 as shown below.

Claim Objections

Claim 6 is objected to because of the following informalities: claim limitations for variables 'X' and 'Y' that are not present in the peptides recited in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is analogous to insertion of genetic material of a virus into the host cell wherein the genetic material (DNA, mRNA of the virus) is transfected to host cell and protein coat of the virus made of peptide represents the polyacetal-peptide given the broad definition of poly-acetal peptide as "copolymers of other recurring units" (page 10, [0033]). Therefore, the invention as recited claims a non-statutory subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant application applicants claim a complex for delivering a polynucleotide to a cell, comprising: (a) a polynucleotide and (b) a biodegradable polyacetal-peptide. Applicants also claim peptides comprises of 2 to 45 amino acids with at least one or more arginine or lysine amino acids from 20 biological amino acids.

The MPEP clearly states that the purpose of the written description is to ensure that the inventor had possession of invention as of the filing date of the application, of the subject matter

later claimed by him. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997). The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the application. These include, "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed invention is sufficient" MPEP 2163.

In the instant application, claim as recited encompasses several classes of polynucleotides such as DNA, RNA, plasmid DNA, antisense DNA, DNA oligomers (oligonucleotides), SiRNA, ribozymes and aptamers. Thus, applicants are claiming any and all different classes of polynucleotides having no regard to size and structure of different classes of polynucleotides, which represents the whole genome (DNA) of organisms consisting of billions of base pairs. The specification provides the example of a single polynucleotide in the form of transfection of plasmid pCMV-EGFP in example 5. The claims as recited and the encompasses any and all polynucleotides of aforementioned classes of any size and structural features wherein either the specification as disclosed or the sequence listing as presented provide adequate support the claims commensurate with the scope of the instant claims. The disclosure

of one plasmid DNA towards claiming unknown number of polynucleotides of unknown size, sequence and structure is vastly inadequate to support a claim that encompasses. With regards to genus, according to MPEP Ch. 2163, "[f]urther, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated: "[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials". The disclosure must describe a sufficient number of species to reflect variation within the genus that corresponds to functional role associated with them. Although, the MPEP does not define what constitute a sufficient number of representative species to reflect the variation within a genus, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In Gostelli, the court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

In addition to this, applicants claim (claims 1-4) peptides that comprises of 2-45 amino acid residues with at least one or more arginine or lysine residues from 20 biological amino acids. And claim 11 is drawn to polyacetal-peptide represented by formula (I) or (II). The claim as recited encompasses innumerable number of peptides of size that varies from a dipeptide to a peptide comprising 45 amino acids. The claims as recited and the specification as disclosed does not adequately support the claim as recited because, the sequence listing in the instant application contains only 11 peptide sequences and hence does not commensurate with the

scope of the claimed invention. The specification defines the polyacetal-peptide as "copolymers and thus may contain two or more different recurring units" (page 10, [0033]), definition encompasses any and all of afore-described peptides with the polymers of formulae I or II. The specification only provides support for the copolymer of formula I and SEQ ID NO: 8. Thus the specification as disclosed is vastly inadequate to support the claim as recited.

Therefore, the claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kakizawa, 2001, Biomacromolecules, 2, 491-497.

In the instant application applicants claim a complex for delivering a polynucleotide to a cell, comprising: (a) a polynucleotide and (b) a biodegradable polyacetal-peptide.

The reference of Kakizawa teaches a complex (micelle) composed of copolymer of polyethyleneglycol (PEG) and poly-L-lysine for the delivery of antisense DNA (title and abstract). The reference discloses that micelles dissociate in the presence of glutathione (GSH) at a concentration comparable to intracellular environment featuring the potential ability of this

system for intracellular oligonucleotide (ODN) delivery (abstract). This meets the limitations of claims 1-3. The fact that the poly-lysine is a peptide comprising 2-45 amino acids and especially lysine meets the limitation of claim 4. Thus claims 1-4 are anticipated by the reference of Kakizawa.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 03/078576 A2 of Yu, et al., as evidenced by Terwilliger, et al., 1982, Biophys. J., 37, 353-361.

In the instant application applicants claim a complex for delivering a polynucleotide to a cell, comprising: (a) a polynucleotide and (b) a biodegradable polyacetal-peptide.

Yu et al., discloses a vector for transfecting a eukaryotic cell comprising a nucleic acid, a nucleic acid binding polymer and a membrane active peptide (page 34, claim 1 and 37 of the cited reference) wherein the nucleic acid is selected from DNA, RNA, DNA/RNA hybrid (page 34, claim 3 of the cited reference), further, the DNA is plasmid DNA, or RNA is single, double or SiRNA (page 34, claims 5 and 6 of the cited reference). This meets the limitations of claims 1-3 of the instant application. The reference also discloses that the membrane active peptide is the Mellitin, a 26 amino acid peptide (page 33, lines 4 and 5). According to the supporting evidence reference of Terwilliger, et al., the Mellitin peptide has the sequence NH_3-Gly-Ile-Gly-Ala-Val-Leu-Lys-Val-Leu-Thr-Thr-Gly-Leu-Pro-Ala-Leu-Ile-Ser-Trp-Ile-**Lys-Arg-Lys-Arg**-Gln-Gln-$CONH_2$ which corresponds to SEQ ID NO: 1 of the instant application and also comprises of Lys and Arg residues, thus meeting the limitations of claim 4 of the instant application. Thus the reference of Yu, et al., anticipates the invention of the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10946383. Although, the conflicting claims are not identical, they are not patentably distinct from each other because in the instant application claims are drawn to a complex for delivering a polynucleotide to a cell, comprising: (a) a polynucleotide and (b) a biodegradable polyacetal-peptide. In the copending application, the claims are drawn to a complex for delivering a polynucleotide to a cell, comprising: a polynucleotide, a polycation and an acid-degradable polyanaion.

The difference between the instant application and the pending application is that the pending application uses a polycation.

The use of polycation has been taught by Kakizawa wherein the reference teaches the use of poly-lysine polymer (polycation). Therefore, it would have been obvious to one skilled in the art to modify the instant application with the teachings of kakizawa to arrive at the invention claimed in the copending application. One would have been motivated to do so because such a complex with the use of polycation has been taught by Kakizawa. Therefore, the invention in the copending application is clearly prima facie obvious to one skilled in the art at the time the invention was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Satyanarayana R. Gudibande, Ph.D.
Art Unit 1654

9/26/09
ANISH GUPTA
PRIMARY EXAMINER